

UNITED STATES DISTRICT COURT FOR THE  
NORTHERN DISTRICT OF NEW YORK

JOAN RELYEA

Plaintiff,

v.

ZIMMER, INC.; ZIMMER HOLDINGS,  
INC.; ZIMMER TRI-STATE; ZIMMER  
TRI-STATE d/b/a TRI-STATE  
ORTHOPEDIC; ZIMMER TRI-STATE  
d/b/a ZIMMER, INC.; ZIMMER  
ORTHOPAEDIC SURGICAL  
PRODUCTS, INC.,

Defendants.

**CIVIL ACTION NO:** 5:11-cv-00866  
(TJM) (DEP)

**JURY TRIAL DEMANDED**

**ANSWER TO COMPLAINT AND JURY TRIAL DEMAND BY  
DEFENDANTS ZIMMER, INC., ZIMMER HOLDINGS, INC., ZIMMER TRI-STATE,  
AND ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC.**

The defendants, Zimmer, Inc., Zimmer Holdings, Inc., Orthopaedic Technologies, LLC, d/b/a Zimmer Tri-State (incorrectly named as (1) Zimmer Tri-State, d/b/a Tri-State Orthopaedic, and (2) Zimmer Tri-State, d/b/a Zimmer, Inc.), and Zimmer Orthopaedic Surgical Products, Inc. (collectively, the "Zimmer Defendants"), respond to the Complaint -- Jury Trial Demand ("Complaint") filed by the plaintiff, Joan Relyea ("Plaintiff"), as follows.

**FIRST DEFENSE**

**NATURE OF THE CASE**

1. The Zimmer Defendants deny the allegations in Paragraph 1 of the Complaint.
2. The Zimmer Defendants admit that Zimmer, Inc., designed, manufactured, marketed, and sold the *NexGen* LPS-Flex femoral component, which was an additional component in the *NexGen* brand of products. The Zimmer Defendants further admit that the

LPS-Flex femoral component is designed to safely accommodate deep flexion. The Zimmer Defendants deny the remaining allegations in Paragraph 2 of the Complaint.

3. Paragraph 3 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 3 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants admit that femoral, tibial, and patellar components can be implanted simultaneously during knee replacement surgery and deny any remaining allegations in Paragraph 3 of the Complaint.

4. The Zimmer Defendants deny the allegations in Paragraph 4 of the Complaint.

5. The Zimmer Defendants deny the allegations in Paragraph 5 of the Complaint.

#### **PARTIES**

6. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 6 of the Complaint and, therefore, deny them.

7. The Zimmer Defendants admit the allegations in Paragraph 7 of the Complaint.

8. The Zimmer Defendants admit the allegations in Paragraph 8 of the Complaint.

9. The Zimmer Defendants admit that Orthopaedic Technologies, LLC, doing business as Zimmer Tri-State, is headquartered in Mount Laurel, New Jersey. The Zimmer Defendants deny the remaining allegations in Paragraph 9 of the Complaint.

10. The Zimmer Defendants admit that Zimmer Surgical, Inc., formerly known as Zimmer Orthopaedic Surgical Products, Inc., has its principal place of business in Dover, Ohio, but deny the remaining allegations in Paragraph 10 of the Complaint.

11. The Zimmer Defendants admit that Zimmer, Inc., developed, designed, tested, manufactured, distributed, marketed, and sold a variety of knee replacement products under the

Zimmer *NexGen* brand, including the *Gender Solutions* LPS-Flex. The Zimmer Defendants admit that products developed, designed, tested, manufactured, distributed, and marketed by Zimmer, Inc., are sold in multiple locations around the world, including within the State of New York. The Zimmer Defendants deny the remaining allegations in Paragraph 11 of the Complaint.

#### **JURISDICTION AND VENUE**

12. The Zimmer Defendants admit the allegations in Paragraph 12 of the Complaint.

13. The Zimmer Defendants admit that Zimmer, Inc., sold products within the area that includes the Northern District Of New York, but lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 13 of the Complaint and, therefore, deny them.

#### **FACTUAL BACKGROUND** **KNEE REPLACEMENT BACKGROUND**

14. Paragraph 14 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 14 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

15. Paragraph 15 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 15 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

16. Paragraph 16 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 16

can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

17. Paragraph 17 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 17 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

18. Paragraph 18 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 18 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

19. Paragraph 19 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 19 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

20. The first sentence of Paragraph 20 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants; the second sentence is unintelligible in its use of the undefined phrase "psychical burden." To the extent Paragraph 20 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

21. Paragraph 21 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 21 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

22. Paragraph 22 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 22 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

23. Paragraph 23 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 23 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

24. Paragraph 24 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants, and further includes Plaintiff's global characterization of individual patient outcomes to which it is impossible to respond on a comprehensive basis. To the extent that Paragraph 24 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

#### **ZIMMER NEXGEN KNEE FACTS**

25. The Zimmer Defendants admit that Zimmer Manufacturing Company was founded in 1927. The Zimmer Defendants admit that Zimmer, Inc., designs and manufactures a wide range of orthopaedic devices. The Zimmer Defendants deny the remaining allegations in Paragraph 25 of the Complaint.

26. The Zimmer Defendants deny the allegations in Paragraph 26 of the Complaint.

27. The Zimmer Defendants admit that in 1999 the FDA cleared for marketing Zimmer, Inc.'s *NexGen* LPS-Flex femoral component; admit that the LPS-Flex includes features designed to safely accommodate flexion greater than 120 degrees; and admit that the LPS-Flex is

designed to safely accommodate flexion up to 155 degrees. The Zimmer Defendants deny the remaining allegations in Paragraph 27 of the Complaint.

28. The Zimmer Defendants admit that in 2006 the FDA cleared for marketing Zimmer, Inc.'s *Gender Solutions* CR-Flex and LPS-Flex femoral components; admit that the *Gender Solutions* CR-Flex and LPS-Flex are semi-constrained, non-linked, condylar knee components that include features designed to safely accommodate flexion greater than 120 degrees; and admit that the *Gender Solutions* CR-Flex and LPS-Flex are designed to safely accommodate flexion up to 155 degrees. The Zimmer Defendants deny the remaining allegations in Paragraph 28 of the Complaint.

29. The Zimmer Defendants admit that in recognition of the anatomical differences between male and female patients, Zimmer, Inc.'s *Gender Solutions* line of knee components includes engineering features that address the distinctive characteristics typically seen in a female knee. The Zimmer Defendants deny the remaining allegations in Paragraph 29 of the Complaint.

30. The Zimmer Defendants admit that Zimmer, Inc.'s *Gender Solutions* line of knee components includes engineering features that address the distinctive characteristics typically seen in a female knee, and further admit that certain published materials regarding those components reference these design goals. The Zimmer Defendants deny the remaining allegations in Paragraph 30 of the Complaint.

31. The Zimmer Defendants admit that in 2007 the FDA cleared for marketing Zimmer, Inc.'s *Gender Solutions* Porous LPS-Flex, and deny the remaining allegations in Paragraph 31 of the Complaint.

32. The Zimmer Defendants admit that Zimmer, Inc., manufactured, labeled, distributed, supplied, marketed, and advertised a variety of knee replacement products under the Zimmer *NexGen* brand, including the *Gender Solutions* LPS-Flex, and further caused products under the *NexGen* brand to be placed in the stream of commerce throughout the United States. The Zimmer Defendants deny the remaining allegations of paragraph 32 of the Complaint.

33. The Zimmer Defendants admit that Zimmer, Inc., submitted regulatory filings to the United States Food & Drug Administration, which resulted in the clearance of a variety of knee replacement products sold under the Zimmer *NexGen* brand, including the *Gender Solutions* LPS-Flex. The Zimmer Defendants deny the remaining allegations in Paragraph 33 of the Complaint.

34. The Zimmer Defendants admit that Zimmer, Inc., designed, assembled, manufactured, marketed, distributed, packaged, labeled, processed, supplied, promoted, and sold a variety of knee replacement products under the Zimmer *NexGen* brand, including the *Gender Solutions* LPS-Flex, and further admit that the knee replacement products sold under the *NexGen* brand include a Package Insert containing warnings and related information regarding the products. The Zimmer Defendants deny the remaining allegations in paragraph 34 of the Complaint.

35. The Zimmer Defendants admit that Zimmer, Inc., submitted regulatory filings to the United States Food & Drug Administration regarding a variety of knee replacement products sold under the Zimmer *NexGen* brand, including the *Gender Solutions* LPS-Flex, and further admit that Zimmer, Inc., is subject to regulations and laws pertaining to the design, manufacture, and sale of medical devices in the United States. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph

35 of the Complaint because Plaintiff fails to specify the laws, provisions, rules, and regulations to which they refer and, therefore, the Zimmer Defendants deny the remaining allegations in Paragraph 35.

36. The Zimmer Defendants admit that Zimmer, Inc., has, on numerous occasions, sought FDA approval for its Zimmer *NexGen* knee components, but denies the remaining allegations in Paragraph 36 of the Complaint.

37. The Zimmer Defendants admit that Zimmer, Inc., submitted 510(k) regulatory filings to the United States Food & Drug Administration, which resulted in the clearance of a variety of knee replacement products sold under the *NexGen* brand, including the *Gender Solutions* LPS-Flex. The Zimmer Defendants deny the remaining allegations in Paragraph 37 of the Complaint.

38. The Zimmer Defendants deny the allegations in Paragraph 38 of the Complaint.

39. The Zimmer Defendants admit that Zimmer, Inc., marketed a variety of knee replacement products sold under the Zimmer *NexGen* brand, including the *Gender Solutions* LPS-Flex, and further admit that *NexGen* knee replacement products are safe and effective in the treatment of the class of patients for which the products were intended when implanted and used as intended. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 39 and, therefore, deny them.

40. The Zimmer Defendants admit that Zimmer, Inc., marketed a variety of knee replacement products under the Zimmer *NexGen* brand, including the *Gender Solutions* LPS-Flex; admit that the *Gender Solutions* LPS-Flex includes engineering features that address the distinctive characteristics typically seen in a female knee; admit that the *Gender Solutions* LPS-Flex includes features designed to safely accommodate flexion greater than 120 degrees; and



admit that the *Gender Solutions* LPS-Flex is designed to safely accommodate flexion up to 155 degrees. The Zimmer Defendants deny the remaining allegations in Paragraph 40 of the Complaint.

**ZIMMER NEXGEN KNEE HIGH FLEX PROBLEMS**

41. The Zimmer Defendants deny the allegations in Paragraph 41 of the Complaint.

42. Paragraph 42 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 42 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

43. Paragraph 43 of the Complaint includes Plaintiff's characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 43 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

44. The Zimmer Defendants deny the allegations in Paragraph 44 of the Complaint.

45. The Zimmer Defendants deny the allegations in Paragraph 45 of the Complaint.

46. The Zimmer Defendants deny the allegations in Paragraph 46 of the Complaint.

47. The Zimmer Defendants deny the allegations in Paragraph 47 of the Complaint.

**FACTUAL ALLEGATIONS**

48. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 48 of the Complaint and, therefore, deny them.

49. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 49 of the Complaint and, therefore, deny them.

50. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 50 of the Complaint and, therefore, deny them.

51. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 51 of the Complaint and, therefore, deny them.

52. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 52 of the Complaint and, therefore, deny them.

53. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 53 of the Complaint and, therefore, deny them.

54. The Zimmer Defendants deny the allegations in Paragraph 54 of the Complaint.

55. The Zimmer Defendants deny the allegations in Paragraph 55 of the Complaint.

56. The Zimmer Defendants deny the allegations in Paragraph 56 of the Complaint.

57. The Zimmer Defendants deny the allegations in Paragraph 57 of the Complaint.

#### **COUNT I – STRICT LIABILITY**

58. The Zimmer Defendants incorporate each and every paragraph in this Answer as if fully set forth herein.

59. The Zimmer Defendants admit Zimmer, Inc., developed, tested, manufactured, marketed, and sold a variety of products under the Zimmer *NexGen* brand, including the *Gender Solutions* LPS-Flex, and admit they knew that certain products would be implanted during knee replacement surgery, but the Zimmer Defendants deny the remaining allegations in Paragraph 59 of the Complaint.

60. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 60 of the Complaint and, therefore, deny them.

61. The Zimmer Defendants deny the allegations in Paragraph 61 of the Complaint.

- 62. The Zimmer Defendants deny the allegations in Paragraph 62 of the Complaint.
- 63. The Zimmer Defendants deny the allegations in Paragraph 63 of the Complaint.
- 64. The Zimmer Defendants deny the allegations in Paragraph 64 of the Complaint.
- 65. The Zimmer Defendants deny the allegations in Paragraph 65 of the Complaint.
- 66. The Zimmer Defendants deny the allegations in Paragraph 66 of the Complaint.
- 67. The Zimmer Defendants deny the allegations in Paragraph 67 of the Complaint.
- 68. The Zimmer Defendants deny the allegations in Paragraph 68 of the Complaint.
- 69. The Zimmer Defendants deny the allegations in Paragraph 69 of the Complaint.
- 70. The Zimmer Defendants deny the allegations in Paragraph 70 of the Complaint.
- 71. The Zimmer Defendants deny the allegations in Paragraph 71 of the Complaint.

The concluding paragraph of Count I of the Complaint is a prayer for relief. The Zimmer Defendants deny Plaintiff is entitled to the relief sought.

#### **COUNT II – NEGLIGENT FAILURE TO WARN**

72. The Zimmer Defendants incorporate each and every paragraph in this Answer as if fully set forth herein.

73. The Zimmer Defendants admit that Zimmer, Inc., developed, tested, manufactured, marketed and sold a variety of products under the Zimmer *NexGen* brand, including the *Gender Solutions* LPS-Flex, but the Zimmer Defendants deny the remaining allegations in Paragraph 73 of the Complaint.

- 74. The Zimmer Defendants deny the allegations in Paragraph 74 of the Complaint.
- 75. The Zimmer Defendants deny the allegations in Paragraph 75 of the Complaint.
- 76. The Zimmer Defendants deny the allegations in Paragraph 76 of the Complaint.
- 77. The Zimmer Defendants deny the allegations in Paragraph 77 of the Complaint.

78. The Zimmer Defendants deny the allegations in Paragraph 78 of the Complaint.

79. The Zimmer Defendants deny the allegations in Paragraph 79 of the Complaint.

80. The Zimmer Defendants deny the allegations in Paragraph 80 of the Complaint.

81. The Zimmer Defendants deny the allegations in Paragraph 81 of the Complaint.

The concluding paragraph of Count II of the Complaint is a prayer for relief. The Zimmer Defendants deny Plaintiff is entitled to the relief sought.

### **COUNT III – NEGLIGENT DESIGN DEFECT**

82. The Zimmer Defendants incorporate each and every paragraph in this Answer as if fully set forth herein.

83. The Zimmer Defendants admit that Zimmer, Inc., researched, developed, manufactured, distributed, marketed, promoted, supplied, and sells Zimmer *NexGen* products, including the *Gender Solutions* LPS-Flex, but deny the remaining allegations in Paragraph 83 of the Complaint.

84. The Zimmer Defendants deny the allegations in Paragraph 84 of the Complaint.

85. The Zimmer Defendants deny the allegations in Paragraph 85 of the Complaint.

86. The Zimmer Defendants deny the allegations in Paragraph 86 of the Complaint.

87. The Zimmer Defendants deny the allegations in Paragraph 87 of the Complaint.

88. The Zimmer Defendants deny the allegations in Paragraph 88 of the Complaint.

89. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 89 of the Complaint and, therefore deny them.

90. The Zimmer Defendants deny the allegations in Paragraph 90 of the Complaint.

91. The Zimmer Defendants deny the allegations in Paragraph 91 of the Complaint.

92. The Zimmer Defendants deny the allegations in Paragraph 92 of the Complaint.

93. The Zimmer Defendants deny the allegations in Paragraph 93 of the Complaint.

The concluding paragraph of Count III of the Complaint is a prayer for relief. The Zimmer Defendants deny Plaintiff is entitled to the relief sought.

**COUNT IV – NEGLIGENCE**

94. The Zimmer Defendants incorporate each and every paragraph in this Answer as if fully set forth herein.

95. The Zimmer Defendants deny the allegations in Paragraph 95 of the Complaint.

96. The Zimmer Defendants deny the allegations in Paragraph 96 of the Complaint.

97. The Zimmer Defendants deny the allegations in Paragraph 97 of the Complaint.

98. The Zimmer Defendants deny the allegations in Paragraph 98 of the Complaint.

99. The Zimmer Defendants deny the allegations in Paragraph 99 of the Complaint.

100. The Zimmer Defendants deny the allegations in Paragraph 100 of the Complaint.

101. The Zimmer Defendants deny the allegations in Paragraph 101 of the Complaint.

102. The Zimmer Defendants deny the allegations in Paragraph 102 of the Complaint.

103. The Zimmer Defendants deny the allegations in Paragraph 103 of the Complaint.

The concluding paragraph of Count IV of the Complaint is a prayer for relief. The Zimmer Defendants deny Plaintiff is entitled to the relief sought.

**COUNT V – BREACH OF EXPRESS WARRANTY**

104. The Zimmer Defendants incorporate each and every paragraph in this Answer as if fully set forth herein.

105. The Zimmer Defendants deny the allegations in Paragraph 105 of the Complaint.

106. The Zimmer Defendants deny the allegations in Paragraph 106 of the Complaint.

107. The Zimmer Defendants deny the allegations in Paragraph 107 of the Complaint.

108. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 108 of the Complaint and, therefore, deny them.

109. The Zimmer Defendants deny the allegations in Paragraph 109 of the Complaint.

110. The Zimmer Defendants deny the allegations in Paragraph 110 of the Complaint.

111. The Zimmer Defendants deny the allegations in Paragraph 111 of the Complaint.

112. The Zimmer Defendants deny the allegations in Paragraph 112 of the Complaint.

The concluding paragraph of Count V of the Complaint is a prayer for relief. The Zimmer Defendants deny Plaintiff is entitled to the relief sought.

#### **COUNT VI – BREACH OF IMPLIED WARRANTY**

113. The Zimmer Defendants incorporate each and every paragraph in this Answer as if fully set forth herein.

114. The Zimmer Defendants deny the allegations in Paragraph 114 of the Complaint.

115. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 115 of the Complaint and, therefore, deny them.

116. The Zimmer Defendants deny the allegations in Paragraph 116 of the Complaint.

117. The Zimmer Defendants deny the allegations in Paragraph 117 of the Complaint.

118. The Zimmer Defendants deny the allegations in Paragraph 118 of the Complaint.

119. The Zimmer Defendants deny the allegations in Paragraph 119 of the Complaint.

The concluding paragraph of Count VI of the Complaint is a prayer for relief. The Zimmer Defendants deny Plaintiff is entitled to the relief sought.

#### **COUNT VII – NEGLIGENT MISREPRESENTATION**

120. The Zimmer Defendants incorporate each and every paragraph in this Answer as if fully set forth herein.

121. The Zimmer Defendants deny the allegations in Paragraph 121 of the Complaint.

122. The Zimmer Defendants deny the allegations in Paragraph 122 of the Complaint.

123. The Zimmer Defendants deny the allegations in Paragraph 123 of the Complaint.

124. The Zimmer Defendants deny the allegations in Paragraph 124 of the Complaint.

125. The Zimmer Defendants deny the allegations in Paragraph 125 of the Complaint.

126. The Zimmer Defendants deny the allegations in Paragraph 126 of the Complaint.

127. The Zimmer Defendants deny the allegations in Paragraph 127 of the Complaint.

128. The Zimmer Defendants deny the allegations in Paragraph 128 of the Complaint.

The concluding paragraph of Count VII of the Complaint is a prayer for relief. The Zimmer Defendants deny Plaintiff is entitled to the relief sought.

#### **COUNT VIII – VIOLATION OF CONSUMER PROTECTION LAWS**

129. The Zimmer Defendants incorporate each and every paragraph in this Answer as if fully set forth herein.

130. The Zimmer Defendants deny the allegations in Paragraph 130 of the Complaint.

131. Paragraph 131 of the Complaint requires no response from the Zimmer Defendants. To the extent that Paragraph 131 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

132. The Zimmer Defendants deny the allegations in Paragraph 132 of the Complaint.

133. The Zimmer Defendants deny the allegations in Paragraph 133 of the Complaint.

134. The Zimmer Defendants deny the allegations in Paragraph 134 of the Complaint.

135. The Zimmer Defendants deny the allegations in Paragraph 135 of the Complaint.

136. The Zimmer Defendants deny each and every allegation in the Complaint unless expressly admitted or otherwise answered herein.

WHEREFORE, the Zimmer Defendants deny that Plaintiff is entitled to any relief demanded in the Complaint.

**GENERAL DENIAL**

Any remaining allegations neither admitted nor denied are hereby expressly denied.

**SECOND DEFENSE**

The Complaint fails to state a claim for which relief may be granted against the Zimmer Defendants.

**THIRD DEFENSE**

The Zimmer Defendants state that Zimmer Holdings, Inc., Zimmer Tri-State, and Zimmer Orthopaedic Surgical Products, Inc., are not proper parties in the case, and this Court lacks personal jurisdiction over some or all of them.

**FOURTH DEFENSE**

If Plaintiff sustained injuries or incurred expenses as alleged, her injuries or expenses were caused in whole or in part by the conduct of one or more persons or entities for whose conduct the Zimmer Defendants were not responsible and with whom the Zimmer Defendants have no legal connection.

**FIFTH DEFENSE**

Any amount that Plaintiff claims as compensatory damages, if the claims for such amounts are not entirely barred, must be diminished proportionately by the fault of Plaintiff and the fault of all others who caused or contributed to cause the harm.



**SIXTH DEFENSE**

If Plaintiff sustained injuries or incurred expenses as alleged, her injuries or expenses were the result of intervening and/or superseding causes, and not as a result of the Zimmer Defendants' alleged acts or omissions.

**SEVENTH DEFENSE**

Plaintiff cannot recover under the Complaint because the Zimmer Defendants complied with all applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States, State of New York, or by an agency of the United States or the State of New York.

**EIGHTH DEFENSE**

Any claims by Plaintiff for inadequate warnings are controlled by and barred under the learned intermediary doctrine.

**NINTH DEFENSE**

Plaintiff cannot recover under the Complaint because the products were in conformity with the generally recognized state of the art at the time they were designed, manufactured, packaged, and labeled.

**TENTH DEFENSE**

If Plaintiff sustained injuries or incurred expenses as alleged, her injuries or expenses were caused by the misuse of the products, and the misuse could not have been intended or reasonably foreseen by the Zimmer Defendants.

**ELEVENTH DEFENSE**

If Plaintiff sustained injuries or incurred expenses as alleged, her injuries or expenses were caused by a modification or alteration of the products, and the modification or alteration was not reasonably expected by the Zimmer Defendants.

**TWELFTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, by the doctrine of federal preemption.

**THIRTEENTH DEFENSE**

Any claim or cause of action that Plaintiff may have had is time barred by applicable periods of prescription, preemption, and/or statute of limitations.

**FOURTEENTH DEFENSE**

The Zimmer Defendants aver that Plaintiff had a duty to mitigate any damages Plaintiff claims to have suffered, which failure bars or reduces any recovery by Plaintiff herein.

**FIFTEENTH DEFENSE**

The Zimmer Defendants plead Act of God, force majeure, or unavoidable accident in defense of Plaintiff's claims.

**SIXTEENTH DEFENSE**

The Zimmer Defendants aver that any product made the subject of this proceeding posed no unreasonable risk of harm and is not otherwise defective.

**SEVENTEENTH DEFENSE**

The Zimmer Defendants aver that any product made the subject of this proceeding was not in a dangerous, defective, or unsafe condition when it left the possession, custody, or control of the Zimmer Defendants.

**EIGHTEENTH DEFENSE**

The Zimmer Defendants allege that any product made the subject of this proceeding was not in a dangerous, defective, or unsafe condition as a result of any action or inaction on the part of the Zimmer Defendants.

**NINETEENTH DEFENSE**

In the event any product made the subject of this proceeding is found to have posed an unreasonable risk of harm, is found to have lacked adequate warnings, or is found to be otherwise defective, all of which is denied, then the Zimmer Defendants assert that it did not know and in light of scientific and technological knowledge reasonably available, could not have known of the design characteristic that caused the damages complained of or the danger of such characteristic or the alternative design sought to be proven by Plaintiff.

**TWENTIETH DEFENSE**

In the event that any product made the subject of this proceeding is found to have posed an unreasonable risk of harm, is found to have lacked adequate warnings, or is found to be otherwise defective, all of which is denied, then the Zimmer Defendants assert that any alternative design sought to be proven by Plaintiff was not feasible in light of scientific, technological knowledge reasonably available at the time of the manufacture, or that exists in economic practicality.

**TWENTY-FIRST DEFENSE**

In the event that any product made the subject of this proceeding is found to have posed an unreasonable risk of harm, is found to have lacked adequate warnings, or is found to be otherwise defective, all of which is denied, then the Zimmer Defendants assert that no warning

was necessary, as any dangers were open and obvious, and/or the product was sold to, leased to, or being used by a sophisticated user.

**TWENTY-SECOND DEFENSE**

Any and all warranties were voided and/or waived by the improper operation, modification and/or failure to inspect or maintain the product made the subject of this proceeding by Plaintiff and/or others for whom the Zimmer Defendants were not responsible.

**TWENTY-THIRD DEFENSE**

To the extent that Plaintiff makes claims for breach of warranties, the Zimmer Defendants assert that such claims are barred by Plaintiff's failure to comply with notice provisions required by New York law and because there is no privity of contract between Plaintiff and the Zimmer Defendants. The Zimmer Defendants further assert all defenses and presumptions provided by the New York Uniform Commercial Code.

**TWENTY-FOURTH DEFENSE**

Plaintiff had full knowledge of, accepted, and/or assumed all risks and possible adverse effects related to the use of any product at issue in this matter. Plaintiff's recovery, therefore, is barred, diminished, reduced, or offset under the principles of assumption of the risk and/or informed consent.

**TWENTY-FIFTH DEFENSE**

The product in question is a prescription medical device that is reasonably safe because reasonable health care providers prescribed the device for a class of patients, knowing the device's foreseeable risks and therapeutic benefits.

**TWENTY-SIXTH DEFENSE**

The Complaint fails to state a claim for punitive damages upon which relief can be granted.

**TWENTY-SEVENTH DEFENSE**

The imposition of punitive damages against the Zimmer Defendants would violate their constitutional rights under the following provisions of the United States Constitution and the comparable provisions of the New York, Delaware, and Indiana Constitutions: The Due Process Clauses in the Fifth and Fourteenth Amendments, the Double Jeopardy Clause in the Fifth Amendment, and the Commerce Clause.

**TWENTY-EIGHTH DEFENSE**

Plaintiff's claims are barred to the extent the injuries alleged in the Complaint resulted from a preexisting and/or unrelated medical and/or idiosyncratic reaction to any Zimmer *NexGen* Product and not from any act or omission by any of the Zimmer Defendants or by any defect in any Zimmer *NexGen* product.

**TWENTY-NINTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, pursuant to N.Y. Gen. Bus. § 349(d).

**THIRTIETH DEFENSE**

The Zimmer Defendants hereby give notice that it intends to rely upon any other defense that may become available or appear during the discovery proceedings in this case and hereby reserves its right to amend this answer to assert any such defense.

WHEREFORE, the Zimmer Defendants respectfully request judgment in their favor, dismissal of the Complaint on the merits with prejudice, costs of this action, attorneys' fees, and all other appropriate relief to which they may be entitled.

Dated: New York, New York

August 22, 2011

Respectfully submitted,

/s/Phoebe A. Wilkinson

Phoebe A. Wilkinson, Bar Roll No. 517041

CHADBOURNE & PARKE, LLP

30 Rockefeller Plaza

New York, NY 10112

Telephone: (212) 408-1157

Facsimile: (646) 710-1157

[pwilkinson@chadbourne.com](mailto:pwilkinson@chadbourne.com)

Attorneys for the defendants, Zimmer, Inc., Zimmer Holdings, Inc., Orthopaedic Technologies, LLC, d/b/a Zimmer Tri-State (incorrectly named as Zimmer Tri-State, d/b/a Tri-State Orthopaedic, and Zimmer Tri-State, d/b/a Zimmer, Inc.), and Zimmer Orthopaedic Surgical Products, Inc.

Of Counsel:

Andrea Roberts Pierson, Atty. No. 18435-49-A

Haroon Anwar, Atty. No. 29135-5310

BAKER & DANIELS

300 North Meridian Street, Suite 2700

Indianapolis, IN 46204

Telephone: (317) 237-0300

Facsimile: (317) 237-1000

[andrea.pierson@bakerd.com](mailto:andrea.pierson@bakerd.com)

[haroon.anwar@bakerd.com](mailto:haroon.anwar@bakerd.com)

**CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing ANSWER TO COMPLAINT -- JURY DEMAND BY DEFENDANTS ZIMMER, INC., ZIMMER HOLDINGS, INC., ZIMMER TRI-STATE, AND ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC., has been served via the Court's electronic filing system on the 22<sup>nd</sup> day of August, 2011, upon the following counsel of record:

Ari Kresch  
KRESCH OLIVER PLLC  
24100 Southfield Road, Ste. 305  
Southfield, MI 48075  
aoliver@krescholiver.com

/s/ Phoebe A. Wilkinson